codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF CONTROL MEASURES

Prepared by the United States of America with the assistance of Australia, Canada, France, Germany, Italy, New Zealand, Norway, Spain, Sweden, Thailand, the International Dairy Federation, the International Federation of Environmental Health, and the International Commission on Microbiological Specifications for Foods

Governments and interested international organizations are invited to submit comments on the attached Draft Code at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by I February 2005.**

BACKGROUND

At the 36th Session of the Codex Committee on Food Hygiene (CCFH), the United States on behalf of its drafting partners presented the Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures (the draft Guidelines). Considerable progress had been made on the Guidelines by an electronic drafting group for the 36th Session of CCFH, but the Committee recommended further drafting at Step 2. Therefore, the Committee delayed detailed discussion of the draft Guidelines until the 37th meeting.

The Committee recommended that the drafting group further revise the draft Guidelines by exploring the relationship of validation to good hygiene practices, HACCP, and risk assessment, to clarify the respective roles of industry and the competent authority, to consider validation in the context of equivalency, and to simplify the document to facilitate its application in smaller and less developed businesses. The Committee also recommended that the drafting group consider whether the document could be presented as a stand alone document or whether it should be an attachment/annex to another document on food hygiene and clarify the relationship between these Guidelines and other documents developed or under development by other organizations.

REVISED DOCUMENT

The drafting group met on 27-28 September 2004 to revise the document based on guidance from CCFH at its 36th meeting. The revised document is attached to this letter. In revising the document, the drafting group made the implicit decision that the document should not be annexed to another document. Likewise, while the drafting group did consider the subject in relation to documents under development by other organizations, it felt that, while these documents are useful and may be appropriate for citation with the current document, the subject is one that Codex Alimentarius should overtly consider and provide specific guidance to its members, particularly in relation to the need to articulate to the member nations a general framework for validation within Codex Alimentarius food hygiene documents.

The drafting group made significant progress on the following aspects of the Guidelines:

- Revising several definitions to make them consistent, to the extent possible, with definitions found in the HACCP Annex to the *International Recommended Code of Practice: General Principles of Food Hygiene*.
- Clarifying the respective roles of industry and the competent authority in validation and the relationship of validation to HACCP, good hygiene practices, and appropriate level of protection.
- Simplifying the structure of the document to make it easier to follow the validation process.
- Focusing the content of the document on the process of validation and moving other related material to an Annex.

RECOMMENDATION

The drafting group consider that the Proposed Draft Guidelines for the Validation of Control Measures has significantly progressed. In recognition of the progress made on the draft Guidelines, the drafting group recommends that the Committee advance the document to Step 5 with the recommendation that the Commission omit Step 6 and 7 and adopt the guidelines at Step 8.

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF CONTROL MEASURES

INTRODUCTION

In the current environment of system-based food safety controls that provide flexibility with the selection of control measures, validation of these control measures acquires increased importance. It is through the validation process that one demonstrates that the selected control measures actually are capable, on a consistent basis, of achieving the intended level of hazard control. It is important to note that, while the initial demonstration of achievement of the desired food safety outcome is validation, the on-going demonstration that the selected control measures are being delivered appropriately is achieved by monitoring and verification.

These guidelines present information on the concept and nature of validation, steps prior to validation, the validation process, priorities for validation, limitations to validation, and the need for re-validation. These guidelines also address the difference between validation and verification and the relationship of HACCP to the validation of food hygiene control measures. Annex I provides explanatory material on the nature of control measures for food hygiene.

It is important to make a clear distinction between the role of industry and the role of the competent authority in validating control measures. Industry is responsible for validation of control measures, while the competent authority ensures that industry has effective systems for validation and verifies that control measures are appropriately validated. Governments may provide advice to industry on how to conduct validation studies and how validated control measures should be implemented. In certain instances, especially where the resources are not available to conduct such studies, governments or international organizations may conduct validation studies, e.g., for developing countries or segments of the industry.

II. SCOPE

These guidelines apply to validation of the full range of control measures intended to control microbial, chemical or physical hazards within the food chain, including primary production, processing, distribution, storage, retail and consumer handling of any type of food. These guidelines are intended as advice to industry and governments on the validation of individual control measures, a limited combination of control measures or of entire sets of control measure combinations forming a food safety control system (e.g. HACCP, GHP).

III. DEFINITIONS[1]

Appropriate Level of Protection (ALOP): The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.[2]

Control Measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[3]

Food Safety Control System: The combination of control measures that, when taken as whole, ensures that food is safe for its intended use, e.g., meets established POs or FSOs, as appropriate.

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[1] In many cases, existing definitions such as those contained in the SPS Agreement, the General Principles of Food Hygiene, HACCP Annex and the CCFH Risk Management document, were suitable for use in this document. In other cases, where a definition was too limiting outside of its original context (e.g., some HACCP Annex definitions), another definition was developed that was more suitable for use within the context of these guidelines.

[2] WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The term Member refers to countries.

[3] *International Recommended Code of Practice: General Principles of Food Hygiene*, CAC/RCP1-1969, Rev. 3 (1997), HACCP Annex.

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of health protection.[4]

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.[5]

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before time of consumption that provides or contributes to an FSO or ALOP, as applicable.[6]

Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.[7]

Validation: Obtaining evidence that control measures are capable of being consistently effective.[8]

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure(s) is or has been operating as intended.[9]

IV. CONCEPT AND NATURE OF VALIDATION.

The control of hazards potentially associated with foods typically involves the application of control measures at specific points in the food continuum, from primary production, through processing, to consumption. The overall safety of a food depends upon the combined effect of control measures that are applied under direct control of food manufacturers and those which are applied in other steps of the food chain over which manufacturers have no direct control (e.g., measures that are applied during primary production as well as during distribution, retail sale and consumer handling).

The range of control measures is extensive and can be broadly classified into three groups according to their specific purpose to control initial hazard levels, prevent increase of hazard levels, or reduce hazard levels. The nature of control measures in the context of food hygiene is described in Annex I.

Before a control measure can be implemented in practice, the intended performance needs to be confirmed by the process referred to as validation. Validation can also be applied to defined combinations of control measures to be applied at a particular step in the food continuum or to entire sets of control measure combinations forming a food safety control system (e.g., HACCP, GHP).

Validation requires that performance be measured against an expected outcome. For validation of an individual control measure or a defined combination of control measures, the expected outcome frequently will be expressed in terms of a performance criterion (e.g., reduction of the level of *Salmonella* by 99.999% [5-log reduction]). For validation of a food safety control system, the expected outcome is frequently expressed in terms of a performance objective established for the end product (e.g. maximum level of *Salmonella* to be <0.04 cfu/g or maximum frequency of recontamination with *Staphylococcus aureus* to be <1/5000 units). Validation on the basis of a performance objective can, under certain circumstances, be focused on an important individual or a defined combination of control measures in the food safety control system.

The type of control measures can influence the approaches selected for validation. For some control measures, evidence that a control measure is capable of being consistently effective can be obtained through direct experimental scientific studies and data collection (e.g. thermal treatment, modification of pH, refrigerated storage). For other control measures, alternative approaches are needed. For example, the effectiveness of certain recommended agricultural practices, animal production practices and employee

[4] Definition accepted for inclusion in Procedural Manual as per ALINORM 04/27/33A, Appendix II.
[5] Ibid.
[6] Ibid.
[7] Derived from *International Recommended Code of Practice: General Principles of Food Hygiene*, CAC/RCP1-1969, Rev. 3 (1997), HACCP Annex, but was expanded because control measures can include more than HACCP controls.
[8] Ibid.
[9] Ibid.

hygiene programs may require consideration of past observations, as direct experimental studies in these cases are difficult or easily confounded.

Validation is performed at the time new control measures or a new food safety control system is designed, or when changes indicate the need for re-validation, to confirm that the control measures or food safety control systems, when implemented as intended, are capable of controlling the hazard to the appropriate level and that this level of control can be achieved consistently. Validation of control measures or food safety control systems is performed before their actual implementation.

Relationship of Validation to Verification and Monitoring

Validation of food hygiene control measures is different from both verification and monitoring. Validation focuses on the collection and evaluation of scientific technical and observational information to determine whether the control measures are capable, if implemented, of controlling the hazard to the appropriate level and that this level of control can be achieved consistently. This is in contrast to monitoring and verification, which both take place only after the validated control measures have been implemented.

Monitoring is the on-going collection of information on a control measure at the time the control measure is applied (e.g., determining product temperature during cooking, cooling, or storage). The information establishes that the measure is meeting or functioning within established limits. Monitoring activities are typically focused on "real-time" measurements and are generally focused on the performance of a specific control measure.

Verification is used to determine that the control measures have been appropriately implemented (e.g., that monitoring is being conducted and documented as specified) and thus are achieving the level of hazard control required. Verification occurs during or after operation through a variety of activities including observation of monitoring activities and review of records to confirm that implementation of control measures is according to design. For example, observations that temperatures are taken at the frequency and in the manner specified would be a verification activity, as would verifying that employees are washing their hands as specified by establishment procedures. Verification typically involves analyses that are supplemental to monitoring, and often includes analyses that are not considered "real-time". Verification can focus on a single control measure (e.g., review of monitoring records), or may evaluate combinations of control measures or the entire food safety control system (e.g., microbiological analysis of end products for process control).

Relationship of Validation to the Appropriate Level of Protection

It is helpful to note the relationship between validation, within the context of these guidelines, and the appropriate level of protection (ALOP). Countries normally express an ALOP in terms of broad public health goals (e.g., reasonable assurance of no harm). Countries may require an objective demonstration that a particular set of control measures or a food safety control system indeed meets their ALOP. In practice, countries may establish an FSO, PO or PC as a practical, measurable articulation of hazard control required to ensure that their ALOP can be achieved. The stringency of hazard control required can be expressed through the choice of PO or PC relative to the acceptable level of the hazard in a product at a specific stage of the food chain. The process of validation will demonstrate whether the selected set of control measures or food safety control system will be effective in reaching the specified PC or PO and the underlying FSO, and thus in ensuring that the ALOP can be achieved.

Relationship of Validation to HACCP

The application of HACCP permits the clear identification of both hazards and effective control measures for the hazards. Validation of control measures, within the context of HACCP, includes identification of hazards, application of control measures, identification of Critical Control Points, selection of Critical Limits, and specification of corrective actions. Successful implementation of HACCP is dependent on its validation by industry or competent authorities against scientifically based criteria. The outcomes of monitoring and verification activities associated with a HACCP system will assist in determining when revalidation of a food safety control system may be necessary.

Validation of control measures, within the context of these guidelines, may be broader in scope than validation of HACCP control measures and may consider controls in areas such as primary production and consumer handling practices. Validation of food hygiene control measures may not be as formally described or as scientifically supported as would a HACCP system. However, the food establishment must have sufficient knowledge and understanding, along with documented evidence, about the control measures employed to ensure that these controls are effective.

V. STEPS PRIOR TO VALIDATION OF CONTROL MEASURES

Prior to the validation of a (set of) control measure(s) by the food establishment, a decision should be made regarding when, where and how validation can be accomplished. For additional guidance, reference is made to General Principles for Food Hygiene and its HACCP Annex and as appropriate to other Codes of Hygienic Practice and Codes of Practice.

Prerequisite steps to validation include:

1) Identify the hazard(s) that can be controlled.

2) Identify the control measures to be validated. Factors that should be considered include:

   - Whether the study is conducted to demonstrate capability of achieving a PC, PO, or FSO,
   - The importance of the control measure as it relates to achieving the expected outcome for control of the hazard,
   - Whether a control measure can be validated by itself or whether combinations of certain control measures should be validated together,
   - The feasibility of conducting the validation,

   Examples of control measures that may need to be validated:

   - The control measures used at critical control points within a HACCP context are generally among the ones that require validation.
   - Heat treatment step in a canning process (Other control points coming before and after the canning process are of lesser importance and may not require validation, though they contribute to the overall food safety control system. However, the degree of variation attributed to these other control points should be sufficiently known so that the validation of the heat treatment step will be adequate with the normal variation in the other control points.).
   - On-farm practices (In some cases, on-farm practices will include control measures that are important to the safety of the finished product and these will need to be validated (e.g., the effective use of competitive exclusion bacteria to prevent colonization of livestock and poultry by human pathogens)).
   - Hurdle technologies (Where hurdle technologies are employed as the means of control, there will be multiple control measures that will need to be validated simultaneously if they act synergistically).

3) Identify the food safety outcome required. Factors to be considered include:

   - Existence of a relevant FSO, PO, and/or PC established at a national or international level
   - Existence of a relevant PO and/or PC defined by industry as part of the design of their particular operation.

   In the absence of previously defined food safety outcomes, appropriate targets should be identified by the competent authority or by industry, as appropriate.

4) Identify whether the (set of) control measure(s) has previously been appropriately validated or whether its performance is so well established for the application under consideration that validation should be considered complete.

5) Identify the appropriate approach to be used for the validation.

VI. THE VALIDATION PROCESS

The establishment responsible for the safety of the food is also responsible for the validation of the control measures or the food safety control system. The competent authority ensures that the establishment has effective systems for validation and verifies that control measures or food safety control systems have been appropriately validated.

The precise approach to validation will depend, among other things, on the nature of the hazard, the nature of the product, the type of control measures or food safety control system selected to control the hazard, and the intended extent of control of the hazard. While the specific validation approach(es) employed may vary substantially, the goal remains the same across all products; i.e., documentation and demonstration that the control measures or food safety control systems employed are properly designed to provide the level of hazard control necessary.

Approaches for validating control measures:

The following approaches to validation may be used individually or in combination, as appropriate.

1. Reference to previous validation studies or historical knowledge of the performance of the control measure(s). For certain well-established processes (e.g., milk pasteurization at 72° C for 15 seconds), it may be sufficient to acquire only the data on the conditions or attributes specific for the operation in question that control a microbiological hazard (e.g., the product temperature and flow rate). Scientific or technical information needed to validate control measures may, in many instances, be available from many sources, including scientific literature, government regulations (and the scientific basis for mandated control measures), guidelines on good hygiene practices and HACCP control measures validated by competent authorities or independent scientific authorities, international standards or guidelines (e.g., Codex Alimentarius), and equipment manufacturer's validation studies. However, if relying on such knowledge, care should be taken to ensure that the conditions of application in a food safety control system are consistent with those identified in the scientific information examined.

2. Scientifically valid experimental trials that document the adequacy of the control measure(s). Laboratory challenge testing designed to mimic process conditions is such an approach as are pilot tests of particular aspects of a food processing system. It may be the case that a set of control measures may be narrowed to a single essential control measure, for example where a pathogen reduction step is employed (e.g., an in-package finished product lethality treatment) whose adequacy may be confirmed and used to validate the entire set of measures. Documentation of log reduction of specified pathogens by specific microbiocidal processes, including appropriate quantitative information on the impact on hazard levels, is an example of this approach to validation. If the risk from the hazard is associated with growth of the pathogen to unacceptable numbers, then the conditions (e.g., product formulation, processing parameters, packaging or method of distribution) that prevent the growth of the pathogen should be validated and documented. An example is control of water activity to prevent growth of *S. aureus*.

Scale up of laboratory-based experimental trials in a pilot plant may be necessary to ensure that the trials properly reflect actual processing parameters and conditions. However, this almost always requires the availability of appropriate non-pathogenic surrogate microorganisms, as viable pathogenic microorganisms should not be purposefully introduced into a food production facility. When surrogate microorganisms are used, validation should cover the appropriateness of the surrogates. Validation may have to be limited to a laboratory/pilot plant if there are no appropriate surrogate microorganisms available that can be used to acquire data under actual production conditions.

3. Collection of data during normal operating conditions in the food operation. In order to validate control measures, it may be necessary to collect appropriate biological, chemical or physical data relating to

the hazard(s) of concern during normal operating conditions in the food operation. For example, when the food safety control system is contingent upon the use of good veterinary practices in the field or good hygienic practices in the processing establishment, it may be necessary to validate these measures through the use of intermediate and/or finished product sampling and testing. Sampling should be based on the use of appropriate statistical sampling plans and validated testing methodology. Sufficient data should be collected that appropriate statistical analysis can be carried out to assess the effectiveness of the control measure being validated.

4. Statistically designed surveys. Statistically designed surveys can be used to document control measures that cannot otherwise be measured. For example, consumer practices related to the storage of perishable products is a control measure that can be measured through surveys. Competent authorities and/or industry can recommend control measures for consumers to apply and the information obtained from surveys can be incorporated into an overall approach for pathogen control. In such instances, procedures should be put into place to ensure that the data supplied to the food manufacturer are appropriate and accurate. This includes acquiring sufficient information such that the variability of factors outside the control of, for instance, a manufacturer (e.g., raw ingredient use at foodservice, retail and in the home and post-manufacturing conditions) can be reasonably estimated. It is important to emphasize that this use of statistical surveys is separate from use of statistical surveys that may be employed in monitoring.

When statistical validation cannot be employed for a control measure that otherwise cannot be measured, the impact of the control measure should be taken into account elsewhere in the design of the process over which control can be maintained. For instance, safety factors can be used when establishing a PC for the control measure and/or a PO for the end product. The extent of variability in areas such as equipment performance and reliability and environmental conditions in the processing plant and potential for recontamination may impact significantly the performance of control measures.

5. Mathematical modeling. Mathematical modeling can be used to estimate the predicted performance of a control measure or combination of control measures, including taking into account variation of individual control measures. An example of this can be found in existing approaches used to validate the adequacy of a product's formulation (e.g., pH, water activity) and packaging to limit pathogen growth under variable storage, distribution and consumer handling conditions.

Steps Involved in the Validation Process

The process of validating control measures includes the following steps:

- Complete the prerequisite steps to validation.
- Assemble documentation of relevant previous validation efforts, evaluate its appropriateness and feasibility for the control measure(s) under consideration and assess the need for supplementary validation.
- If needed, conduct the validation studies, considering the extent of process variability in the study design.
- Document the findings of the validation studies.
- Communicate the findings and their interpretation to decision-makers.

Results of validation studies will either

- Indicate that the hazard can be adequately controlled and, thus, the measure can be implemented, or
- Indicate that the measure is not adequate to achieve the necessary level of control and should not be implemented. This may lead to re-evaluation of process parameters, control measures, the food safety control system design, or other appropriate decisions/actions.

VII. PRIORITIES FOR VALIDATION

In principle, all control measures used to control the various hazards potentially associated with a food product or product group should be validated. In practice, however, resource constraints may prohibit a comprehensive approach to validation and there may be a need to prioritize which control measures are actually validated. The following are some suggested parameters for determining how validation of control measures should be prioritized.

- Level of risk: The higher the likelihood that a loss of control or the inappropriate selection of a (set of) control measure(s) will lead to an adverse health effect from a hazard, and the more severe the adverse health effect which may result, the more attention should be paid to assuring that the (set of) control measure(s) selected are effective.

- Importance of a control measure(s): Validation priority should be given to the most significant control measures in a food safety control system, i.e., prioritization should be done according to the relative importance of a given control measure in the overall scheme of a food safety control system.

- Historical experience: If little or no experience exists with respect to the performance of a control measure in controlling a particular hazard, it becomes more important that validation be undertaken. For many food production and processing scenarios, there is extensive history that specific measures used to control food borne hazards are effective. Care is needed, however, to avoid assuming that a food production or processing system is safe based solely on historical experience. All relevant current information should be considered when evaluating the adequacy of historical information, as it may be outdated. For example, sampling and testing procedures used to obtain the original data may have been insufficient in the context of current capabilities. New strains of microbial pathogens may now exist that do not behave in the same manner as the strains of pathogens or surrogate microorganisms used for determining early food control processes. New epidemiological and/or clinical information may indicate that the previously used control measures were less effective than previously thought.

VIII. LIMITATIONS TO VALIDATION

Validation depends on the application of the best science possible within practical economic and resource constraints. There are several factors, however, which place limits on the level of certainty of the validation. To some extent, limitations in validation can be compensated for through the use of safety factors (i.e., applying appropriate safety margins that exceed the uncertainty consequent with limited validation). The factors that may limit validation, some of which are related to the design of food safety control systems, include the following:

- Performance Target: If a performance target (e.g., ALOP, FSO, PO, or PC) is not available (not pre-established or specified) or not solely dependent on the appropriate level of hazard control at the stage the control measure(s) is to be implemented (this could apply to the FSO and ALOP for instance), it may limit the ability to clearly demonstrate that the desired outcome can be achieved.

- Sampling Plans and Analytical Test Methods: The use of appropriate analytical methodology and statistical-based sampling plans is essential when validating control measures. The reliability of the validation study is directly related to the precision of the analytical methodology used and the statistical sampling plans or experimental designs employed to demonstrate that an outcome has been achieved. Sampling plans should be chosen to obtain the level of certainty desired in the validation study being undertaken, and taking into account any uncertainty arising from the analytical methodology.

- Resource Constraints: Validation activities are often resource intensive. Areas such as validation studies, mathematical modelling or product sampling and analytical testing, particularly when applied in an appropriate statistical fashion, require significant resources. The extent to which sufficient resources are available and such activities can be undertaken will place limits on the ability to develop and validate food hygiene control measures. Necessary assistance, particularly to small and less-developed businesses, should be provided by national and international organizations.

- Steps Beyond the Control of the Validating Establishment: When validating an entire food safety control system, steps beyond the control of the establishment undertaking the validation (e.g., consumer handling and consumption practices) may introduce considerable uncertainty into the validation.

It is important to note that the more uncertainty exists around the ability of the selected control measures to adequately control the hazards targeted, the greater reliance there will be on verification (e.g., end product testing) to ensure that a product is safe. Similarly, if certainty of hazard control can be demonstrated through validation, there is less need for verification. In those instance where there is substantial uncertainty and extensive verification is not be feasible, the stringency of the control measure (or food safety control system) may have to be increased to provide an appropriate measure of assurance that the level of control is consistently met.

IX. NEED FOR RE-VALIDATION

There are many changes that could lead to a need to re-validate a control measure, combination of control measures or the entire food safety control system. Examples include:

- The introduction in the food control system of a new control measure, technology or a piece of equipment that impacts the control of the hazard means that the system or parts of it may need to be revalidated. Similarly, changes made in product formulation or the application of current control measures (e.g., temperature changes) may result in the need for re-validation of control measures. While minor changes are less likely to require re-validation of the control measures, multiple minor changes will almost certainly result in the requirement for re-validation.

- The hazard(s) associated with a food or ingredient changes as a result of (i) higher concentrations of pathogen(s) than originally encountered and accounted for in the design, (ii) a change in response of a hazard to control (e.g., adaptation), (iii) emergence of a previously unidentified hazard, or (iv) new information indicating that the hazard is not being controlled to the level specified (e.g., new epidemiological findings or new analytical technologies) may result in the need for re-validation.

- If monitoring or verification identifies failures above a pre-established rate for which a process deviation cause cannot be identified, re-validation may be needed. Non-compliance with monitoring or verification criteria may indicate a change in the parameters (i.e., the selection and specification of the control measures) on which the design of the food safety control system is based.

ANNEX I NATURE OF CONTROL MEASURES

In the context of these guidelines, a broad range of control measures is used in the food continuum from primary production, processing and manufacturing, transport and distribution, storage and retail to preparation and consumption of the food. Control measures may include a variety of practices applied at various stages (e.g., good agricultural and animal production practices, good hygiene practices during manufacture and processing, good consumer handling practices). Control measures can also encompass sorting based on observation and inspectional procedures (including product sampling and testing), as well as certain types of product labelling (e.g., consumer safe-handling statements). Because of this broad range of control measures, and recognizing that there may be different ways of categorizing control measures, one approach is to categorize control measures as illustrated below, with included examples.

Ensuring control of initial levels of hazard(s)

- Employing good agricultural and animal production practices to minimize contamination during primary production.
- Using vaccines or competitive inhibition/exclusion to minimize microbial pathogens in animals for human consumption.
- Requiring verifiable documentation (e.g., letters of guarantee or certificates of analysis) attesting to the status of microbiological, chemical and physical hazards in the incoming raw material.
- Using sampling and analyses, as necessary, and using appropriate methods based on established criteria to reject unacceptable ingredients or products.

Preventing an unacceptable increase of hazard(s)

- Limiting growth of pathogens during processing, storage and transportation through proper temperature control (e.g., chilling and holding time and temperatures) and product formulation (e.g., acidification, reduction of water activity levels, use of preservatives, use of competitive microflora).
- Using shelf-life determination as a means for ensuring that a product is used or consumed before an unacceptable increase of a hazard.
- Employing good cleaning and disinfection practices to minimize microbial or chemical loads in establishments and/or on processing equipment that would otherwise contaminate the product.
- Establishment of good hygienic practices that minimize product contamination during or after manufacture and prevent cross-contamination between raw and cooked product.
- Using packaging techniques and materials to protect food from contamination.
- Implementing effective controls within the food processing environment (e.g., pest control, housekeeping, etc.)

Reducing the level of hazard(s)

- Destroying pathogens (e.g., disinfectants, pasteurization, commercial sterilization, irradiation, freezing to kill certain parasites) or inactivating chemical hazards in the food.
- Removing pathogens, toxic chemicals or physical hazards in the food (e.g., physical inspection, sorting, trimming, washing, filtration, and centrifugation).